Clinical Trials Strategic Assessment (CTSA)

Working Group Update

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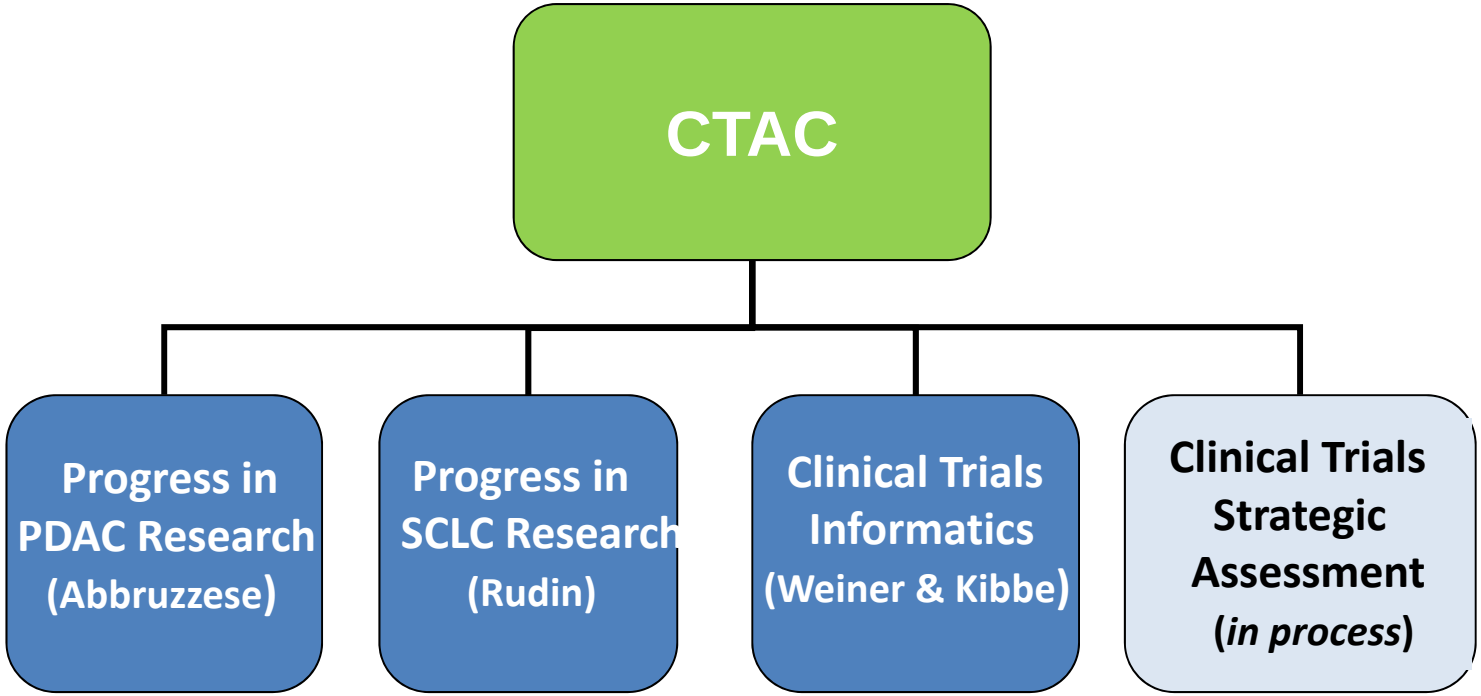
July 13, 2016

CTAC Working Groups - 2016



CTSA Working Group Charge

- **Assess the strategic clinical trial priorities established by the Scientific Steering Committees (SSCs) in 2015**
- **Assess the process for establishing the strategic clinical trial priorities**
- **Assess quality and objectivity of the individual strategic clinical trial portfolio assessments conducted by the SSCs**
- **Perform a cross-portfolio assessment**
  - *Overall cross-portfolio quality*
  - *Cross-portfolio recommendations*
  - *Value of the portfolio assessment process*
  - *Recommendations for future portfolio assessments*

CTSA WG is focused on the ongoing work of the NCTN Groups/NCORP Research Bases and the SSCs and providing advice on mid-course corrections

Implementation of CTSA Working Group

- **Convened in Fall 2016**
  - Delayed in order to incorporate results from pilot assessments of the NCTN breast and gynecological clinical trial portfolios
- **Membership**
  - CTAC members
  - Cancer Center Directors
  - NCTN Group Chairs
  - NCTN Biostatisticians
  - Patient Advocate
- **Deliberations conducted October 2016 – November 2018**
- **Results reported to CTAC July 2017 – November 2018**

Strategic Clinical Trial Priorities

Goal of Strategic Clinical Trial Priorities

Establish a small number of well-defined strategic priorities for trials under the purview of each SSC in order that the investment in NCTN and NCORP clinical trials is focused on addressing the most important and promising clinical questions

Definition of a Strategic Clinical Trial Priority

- **What is a strategic clinical trial priority**
  - Unmet clinical need specific to the disease
  - Important unanswered clinical question with regard to improving disease treatment/symptom management
  - Potential new approach to disease treatment/symptom management
  - Encompasses a wide range of potential trial concepts
- **What is *not* a strategic clinical trial priority**
  - Specific trial idea
  - Broad area of interest for NCI trials (e.g., novel therapies, rare diseases, molecularly targeted therapies)

Establishing Strategic Clinical Trial Priorities
Results of Initial Round

- NCTN Groups* proposed strategic clinical trial priorities for SSC discussion
- Based on presented priorities and other input, each SSC identified a list of priorities- submitted to NCI in June 2015
- Priorities fell into four major categories with highly variable distribution across the SSCs
  - Strategic Clinical Trial Priorities
  - Broad Goals
  - Trial Design Priorities (e.g., molecularly targeted trials, adaptive trials)
  - Translational Research Priorities (e.g., identification of markers associated with outcome, tumor response, risk, etc.)
- NCI recommended and CTAC agreed that assessing the strategic clinical trial priorities and the priority setting process should be included in the CTSA Working Group charge (November 2015)

*NCORP Research Bases proposed priorities for SxQOL trials

Proposed CTSA Working Group Activities
Assessment of Priorities

- Review priorities, their categorization and NCI's operational definition of a strategic clinical trial priority
- Review feedback from CTEP/DCP Medical Officers, SSC Chairs and NCTN Group/NCORP RB representatives on the priorities, their categorization and the priority setting process
- Develop recommendations for refining the process and possibly the operational definition of a strategic clinical trial priority for future rounds of priority setting
- Report to CTAC
  - Assessment of the current priorities
  - Assessment of the operational definition of a strategic clinical trial priority
  - Assessment of the priority setting process
  - Any recommendations for future rounds of priority setting

Proposed Timeline for Analysis of Strategic Clinical Trial Priorities

- June 2015: Strategic clinical trial priorities established by each SSC
- October 2016 – March 2017: CTSA WG assessment of strategic clinical trial priorities and the priority setting process
- July 2017: CTSA WG presents to CTAC results of the assessment

Strategic Clinical Trial Portfolio Assessment

Goal of Strategic Clinical Trial Portfolio Assessment

High level assessment of the overall strength of the NCTN/NCORP clinical trial portfolio

- Assessment of trial portfolios under the purview of each SSC
  - Quality of individual trials within the portfolio
  - Whether the trial portfolio as a whole is addressing the most important clinical questions under the purview of the SSC
- Assessment of the overall strength of NCTN/NCORP clinical trials across portfolios

Strategic Clinical Trial Portfolio Assessment Process

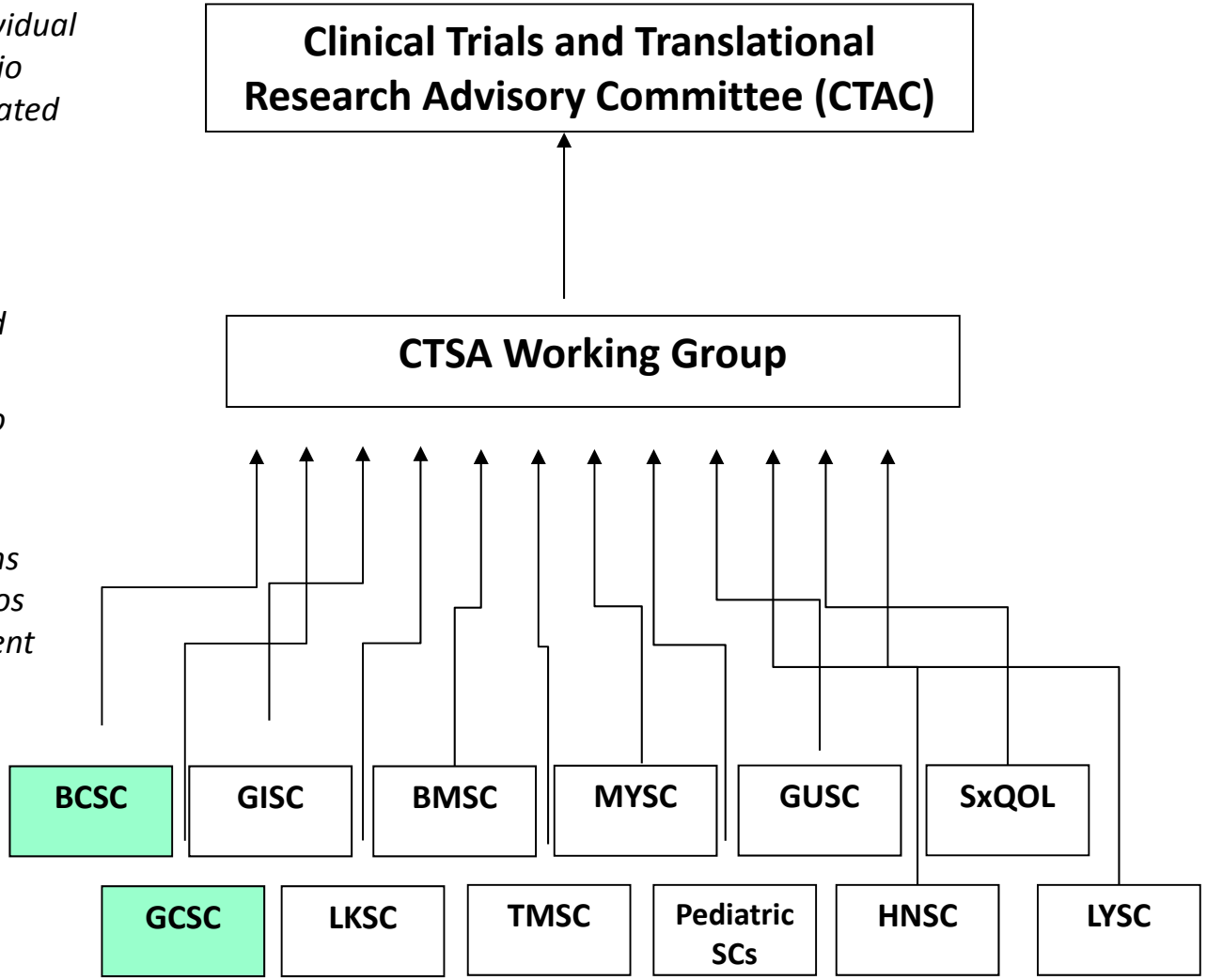
Review and approve individual SSC and cross-portfolio assessments and associated recommendations

Analyze individual assessments of the SSC portfolios for quality and objectivity

Perform a cross-portfolio assessment based on individual assessments

Develop recommendations for improving the portfolios and the portfolio assessment process

Initial assessment of portfolios by SSCs



Lessons Learned from Pilot Strategic Clinical Trial Portfolio Assessments by the BCSC and GCSC

- Assessment was judged to be both valuable and feasible
- Assessment should be conducted every 4-5 years not annually
- Assessment should include all trials open, approved, disapproved or closed since the last assessment and not be limited to trials approved since the last assessment
- Assessment criteria were judged to be appropriate
- Assessment should be conducted as an in-person meeting to facilitate in-depth discussion and development of definitive conclusions and actionable recommendations
- Independent of the Assessment Process accrual performance should be an ongoing activity of the SSC

Proposed Process for Strategic Assessment of SSC Clinical Trial Portfolios Going Forward

- Assessments conducted as in-person, facilitated meetings with duration determined by the size of the portfolio

- Trials included in the assessment
  - All open trials at the time of the assessment
  - All trials approved by the SSC but not yet activated
  - All trials closed for any reason during the period since the previous portfolio assessment
  - Concepts disapproved since the last assessment

- Dimensions of quality assessed for individual trials
  - Clinical importance
  - Scientific contribution
  - Suitability for a publically funded program
  - Extent of competing trials
  - Potential barriers to accrual
  - Alignment with established strategic clinical trial priorities

Proposed Process for Strategic Assessment of SSC Clinical Trial Portfolios Going Forward (cont.)

- Factors assessed for the portfolio as a whole
  - Importance of the clinical questions addressed
  - Distribution across organ sites (if applicable)
  - Range and distribution of clinical conditions
  - Range and distribution of modalities
  - Range and distribution of primary study questions (e.g. new agent, new target, new population, new regimen)
  - Balance of biomarker-driven versus non-biomarker driven trials
  - Balance of innovative, randomized phase 2 trials versus phase 3 trials

- Development of recommendations for improving the portfolio based on results of the assessment

Proposed CTSA Working Group Activities
Analysis of Strategic Clinical Trial Portfolio Assessments

- Evaluate quality and objectivity of the SSC portfolio assessments
- Present results of the analysis of each SSC strategic portfolio assessment to CTAC
- Conduct cross-portfolio assessment
  - Evaluate overall cross-portfolio quality
  - Make recommendations for improving the overall portfolio
  - Assess value of portfolio assessment process
  - Make recommendations on the timing and process for future assessments
- Present results of the cross- portfolio assessment to CTAC

Proposed Timeline for Strategic Clinical Trial Portfolio Assessments

- December 2015 – April 2016: BCSC & GCSC assessment pilots
- January – December 2017: SSC strategic portfolio assessments
- March 2017 – February 2018: CTSA WG analysis of the individual SSC strategic portfolio assessments
- July 2017 – March 2018: CTSA WG presents their analysis to CTAC
- April – September 2018: CTSA WG cross-portfolio assessment
- November 2018: CTSA WG presents their cross portfolio assessment and final strategic portfolio assessment report to CTAC